

## C-16

# Efficacy of Ipilimumab and Nivolumab in Patients with High-grade Neuroendocrine Neoplasms

Taymeyah Al-Toubah<sup>1</sup>, Thorvardur Halfdanarson<sup>2</sup>, Jennifer Gile<sup>2</sup>, Brian Morse<sup>1</sup>, Katelynn Sommerer<sup>1</sup>, Jonathan Strosberg<sup>1</sup>

<sup>1</sup>H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL; <sup>2</sup>Mayo Clinic, Rochester, MN

**BACKGROUND:** Dual checkpoint inhibitor therapy with anti-PD-1 and anti-CTLA-4 therapy has shown promising results in patients with high-grade neuroendocrine neoplasms, demonstrating varying response rates of 9 - 44%. More data are needed to evaluate the true response in a real-world cohort of patients.

**METHODS:** Retrospective study of all patients with high-grade NENs treated at the Moffitt Cancer Center and Mayo Clinic between 9/2017 and 7/2020 who received combination therapy with ipilimumab and nivolumab.

**RESULTS:** 34 patients met eligibility criteria. Patients had received an average of 2 prior lines of therapy, including at least one cytotoxic chemotherapy regimen. 27 (79.4%) of patients had poorly differentiated NECs, and 7 (20.6%) had well-differentiated high-grade NETs. The most common primary site (10, 29.4%) was pancreas; other primary sites of disease included colon (n=5), endometrium (n=3), anorectum (n=2), esophagus (n=2), cervix (n=1), stomach (n=1), small intestine (n=1), and unknown primary (n=9). 5 patients (14.7%) exhibited a best response of PR per RECIST 1.1 criteria, 9 (26.5%) SD, and 17 (50%) PD: 3 patients did not have a follow-up scan as they discontinued treatment shortly after initiation due to clinical progression. ORR was 14.7%, and DCR was 41.2%. Median PFS was 1 month (95% CI, 0.54 - 1.46); median OS from time of treatment initiation was 5.0 months (95% CI, 4.07 - 5.93), and median OS from diagnosis was 14.0 months (95% CI, 11.79 - 16.21). The median duration of treatment was 1 month (range 0 - 10 months). 28 patients discontinued treatment for progression, 4 patients for toxicity, and 2 remain on treatment at the time of data cut off.

12 patients (35%) experienced grade 3 and 4 treatment-emergent toxicities.

**CONCLUSION:** The ipilimumab and nivolumab regimen has modest activity in aggressive and heavily pretreated high-grade NENs who have progressed on prior cytotoxic chemotherapy.

**ABSTRACT ID:** 159